



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Joel R. Studin
Serial No. : 10/829,315
Filed : April 21, 2004
Examiner : Sheikh, Humera N.
Art Unit : 1615
Title : *Method and Composition for the Treatment of Scars*

Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF JOEL R. STUDIN UNDER 37 C.F.R. §1.131

I do hereby declare as follows:

1. **THAT I** received a Bachelor of Science in General Science and Psychology from the University of Rochester, Rochester, NY, in 1975.
2. **THAT I** received a Doctor of Medicine from Mount Sinai Hospital, New York, NY, in 1982.
3. **THAT I** have practiced as a Plastic and Reconstructive Surgeon since 1987.
4. **THAT I** am the inventor of the above-identified application, that I am familiar with the above-identified application, the Office Actions and applied references rendered to date.
5. **THAT Exhibit A** is a Formula Worksheet from an independent laboratory I directed to prepare a formulation called Scar Guard, containing a corticosteroid in a film-forming carrier, prior to September 28, 1999. See Exhibit A, from which all dates and extraneous information have been redacted.
6. **THAT Exhibit B** is a Stability Report Sheet which shows stability testing results of Scar Guard formulation prior to September 28, 1999. See Exhibit B, from which all dates and extraneous information have been redacted.
7. **THAT Exhibit C** is a Facsimile Cover Page from a independent testing facility I directed to test Scar Guard, stating that "clinical testing on

psoriasis indicated that there was a transfer of the corticosteroid into the skin," prior to September 28, 1999. See Exhibit C, from which all dates and extraneous information have been redacted.

8. I further declare that all statements made herein to my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements so made may jeopardize the validity of the document, or application, or any patent issuing therefrom.

4.10.07
Date

Respectfully submitted,


Joel R. Studin

A

LABORATORIES, INC.

*** FORMULA WORKSHEET ***

Page: 1

Formula : SCAR GUARD LIQ

Code:

Description :

Schedule :

Days to exp. :

Where obtained: DFG

Misc.: Therapy:

Date made : / /

Exp. date : / /

AWP per MLS: \$.658 as of:

Estimated time to make: 30 min.

Date: NDC:

COUNSELED: _____

Made by: _____

Verified by: _____

Lot number: _____

Qty made: 100 MLS

CHEMICALS

Name	Form	Quantity used	unit	Lot Number	Exp. Date	Mfg	Ing. Cost
XANTHAN GUM	PODR	.200	GMS	/	/		\$.0104
1 GMS / #500 (formula qty) x #100 (qty made) =	PODR	1.000	GMS	/	/		\$1.0700
HYDROCORTISONE MICONIZED USP	LIQ	10.000	MLS	/	/		\$1.7000
5 GMS / #500 (formula qty) x #100 (qty made) =	SOLN	90.000	MLS	/	/		\$2.1600
SILICONE FLUID 556	SUPL	6.800	UNIT	/	/		\$3.6040
50 MLS / #500 (formula qty) x #100 (qty made) =							
COLLOID FLEXIBLE, USP/NF							
450 MLS / #500 (formula qty) x #100 (qty made) =							
# BRUSH APPLICATOR 15 ML							
34 UNIT / #500 (formula qty) x #100 (qty made) =							
Estimated profit per batch \$							57.26
Total ing. cost							\$8.54

INSTRUCTIONS/NOTES

1. PUT XANTHAN GUM & HC POWDER IN MORTAR & MIX WELL.
2. SLOWLY ADD SILICONE, MIXING WELL
3. SLOWLY ADD ABOUT 100ML OF FLEX COLLODION, MIXING WELL.
4. POUR RESULTANT MIXTURE IN A JAR & ADD REMAINING FLEX COLLODION AND SHAKE VIGOROUSLY UNTIL RESULTANT LIQUID IS HOMOGENIOUS.
5. SHAKE WELL & POUR SMALL AMOUNT INTO A BEAKER AND FILL 15ML BRUSH BOTTLES KEEP SHAKING & FILLING UNTIL ALL BOTTLES ARE FULL.

Stability Report Sheet

Product Description Scar Guard

Product Lab Number G228

Date Manufactured Unknown

Date Bottled

Ref Standard	Date started	Time in	Time out	Date Completed	Comments	Pass/Fail
Dark Stability						Y N
Light Stability						Y N

Oven Stability

month 1		4:00pm	1:30Pm		Yellow, sediment, off-color cap	Y N
month 2						Y N
month 3						Y N
month 4						Y N

Freeze/Thaw

Cycle 1		9:23AM	4:06PM		Pass	Y N
Cycle 2		1:12PM	9:35AM		Pass	Y N
Cycle 3		10:01AM	4:06PM		Pass	Y N

Cool/Heat

Cycle 1		5:03AM	4:06PM		Pass	Y N
Cycle 2		5:06AM	4:20PM		Pass	Y N
Cycle 3		9:06AM	4:06PM		Pass	Y N

UV Stability

Cycle 1		9:00AM	3:00PM		Pass	Y N
Cycle 2		3:00PM	4:00PM		Pass	Y N
Cycle 3		1:00PM	10:00AM		Fail - Color change to yellow	Y N
Cycle 4						Y N

The above analysis were completed by Robert Kozic

The above analysis, laboratory notebooks and pertinent information was reviewed and the results verified by

This product (PASS) (FAIL) the above stability testing on DATE



Tel:

Fax:

FACSIMILE COVER PAGE

To: Christine (Business Fax)	From: Zane Last
Fax #:	Fax #:
Company: Red Rocks Laboratories, Inc.	Tel #:
Subject: Scar Guard & Validation	
Sent:	Pages: 1 (including cover)

MESSAGE:

Christine,

We are able to verify the amount of hydrocortisone in the collodion base as part of the validity and stability testing. While your clinical testing on psoriasis indicated that there was a transfer of the corticosteroid into the skin, your request to assay the actual potency of the delivery of corticosteroids for skin conditions such as psoriasis and eczema would have to be outsourced as they involve either animal or human studies.

Please let me know if you would like us to send this out for quotes.

Thank You,

Zane Last R. Ph.

Confidentiality Notice

This communication is intended for the sole use of the individual to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this communication is not the intended recipient, or the employee or the agent for delivering the communication to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify the sender immediately by telephone call and return the communication to the address above via the United States Postal Service. Thank you.